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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,455	05/09/2001	Arthur J. Blume	2598-4004US1	5124

7590 01/29/2003
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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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.1639

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/852,455	Applicant(s) BLUME ET AL.	
	Examiner T. D. Wessendorf	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11,13,14 and 17-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,4-12,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9,10</u> | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-16 and the species, protein, in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the restriction requirement appears to be incomplete as there is no indication of the classification search groups defined by the Examiner. Since the examiner has not indicated the separate classification, separate status in the art or a different field of search, an examination of the all the pending claims would not impose a serious burden on the Examiner. This is not found persuasive because the restriction requirement does not have to provide the classifications of each group to be complete, as the search is not solely based on the U.S. Patents but on literature searches. These searches are not co-extensive. As stated in the last Office action, the groups of inventions are recognized to have divergent subject matter i.e., distinct and independent from one another. The restriction requirement would indeed imposed undue burden on the examiner. Each of the Groups contains different limitations, a prior art reference encompassing the limitation of one group would not include the limitation present in the other groups.

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The requirement is still deemed proper and is therefore made FINAL.

Claims 2-3, 11 (with respect to the non-elected receptors, transcription and translation regulatory sites), 13-14 and 17-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 1, 4-12 and 15-16 are under examination.

Specification

The disclosure is objected to because: 1) it contains an embedded hyperlink and/or other form of browser-executable code (e.g., page 10, lines 3 and 4; page 11, line 20 and line 30). Applicants are requested to check for other hyperlinks and to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

2) U.S. Patent No. 388 recited at page 19, line 8 is incomplete as the other digits are missing.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors [typographical, grammatical (e.g., page 4, lines 11-12; page 2, line 14) and idiomatic]. Applicants' cooperation is requested

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in correcting any errors of which applicants may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-12, 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide a written description of a method for a binding partner precursor for a target. There is no definition as to what constitute a precursor or what makes a precursor of a binding partner. The specification, page 5, line 9, recites a precursor without describing what is included or excluded from said term. Except for the general term disclosed in the specification, not a single precursor is described in the specification, let alone, a motif derived from said precursor.

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Also, the specification fails to provide an adequate written description for step b of the claimed invention. The specification provides general statements. The exemplification drawn to step b of the claimed invention is nil.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-12, 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method of identifying an amino acid sequence motif i.e., the step prior to screening or expressing the amino acid sequences. Also, claim 1 is indefinite as to the inconsistent used of terminologies "gene product" of the naturally occurring binding partner and protein. The metes and

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bounds of the claimed "precursor" is not clearly set forth in the claims or specification.

B. Claims 7 and 8 are unclear as to the other sequences comprised in the 20 amino acids that would not materially affect the random sequence, especially in the absence of positive support in the specification, as to the other materials that do or do not materially affect the random sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Blume et al (Biopolymers, 2000).

Blume discloses a method of identifying a natural protein ligand, that binds to a target (growth hormone, monoclonal antibody, inter alia) comprising: preparing a phage display library of randomized 20-40-mer (page 349, col. 1 and page 351,

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col. 1)) screening said phage library for consensus or motif sequences that bind to the growth hormone receptors (page 349, col. 2), isolating said peptide with the expressed amino acid motifs that bind to growth hormone, identifying said motif sequences and entering the consensus into the program, Patternfind, which identified the naturally occurring ligand, e.g., p53 as the binding partner, (Figure 5, page 354 and page 355, col. 1). The method steps of Blume which recites specific method steps using specific components in the method anticipates the broadly claimed methods comprising the broad steps containing broad components therein.

Claim 16 is disclosed at page 350, col. 2 of the Blume reference.

Claims 1, 4-5, 9-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraft (The Journal of Biological Chemistry, 1/22/1999).

Kraft basically discloses the same method steps as Blume above. Kraft uses RGD motif to identify the natural ligand, fibronectin that binds to the target $\alpha v \beta 6$ of integrin with the motif as shown at Table III, page 1983. See page 1979, Experimental Procedures up to page 1983 which discloses the search of GEMBL data bases to reveal several binding proteins with consensus sequences as shown in Table III.

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Claim 10 is described by Kraft at page 1979, Experimental Procedures using human integrins.

Claims 15-16 are disclosed at page 1979, col. 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft in view of Kay et al (6,303,574).

Kraft is discussed above. Kraft does not disclose a random sequence comprising about 20-40 amino acids or consists essentially of the 20-40 residues. Kay discloses at col. 5, lines 20-63 a random sequence of 9-45 amino acid residues encompassing a consensus sequence. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add flanking sequences to a consensus sequence of Kraft in the manner as taught by Kay. Adding such flanking sequences in a consensus sequence provides motifs that

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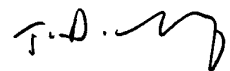
reflect variations in the motif domain binding selectivities or specificities, as taught by Kay. This would provide the motivation to one having ordinary skill in the art to expand or produce a longer length random peptide to locate and fingerprint the motif with high specificity and selectivity.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
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tdw

January 25, 2003